K063255
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510(k) SUMMARY

**SUBMITTER:**

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**CONTACT PERSON:**

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JAN 11 2007

**DATE PREPARED:**

October 26, 2006

**DEVICE TRADE NAME:**

D130 Ph.I.S.I.O. Dideco Kids Neonatal Arterial Filter with 40 micron screen phosphorilcholine coated (hereafter referred to as D130 Ph.I.S.I.O.)

**COMMON NAME:**

Arterial Filter

**CLASSIFICATION NAME:**

Cardiopulmonary Bypass Arterial Line Blood Filter

**PREDICATE DEVICE:**

D736 MICRO 40 Ph.I.S.I.O.: Dideco Newborn-Infant Arterial Filter with Ph.I.S.I.O. coating (Phosphorilcholine coating) as described in K002493 and modified in K033987.

**DEVICE DESCRIPTION:**

The D130 Ph.I.S.I.O. is a sterile, non-pyrogenic disposable filter for use in arterial line of the cardiopulmonary bypass circuit with the flow rate not exceeding 0.7 liters/minute. The D130 Ph.I.S.I.O. is a Neonatal Arterial Filters with 40 micron filter screen designed to remove potentially harmful gaseous emboli, aggregated blood constituents, and particulate debris greater than 40 microns from the arterial line perfusate. The overall dimensions have been reduced in the modified version of the D736 Ph.I.S.I.O. unmodified device resulting in decreased priming volume and maximum blood flow to 0.7 liters/minute. The internal modifications which mainly involve the filter screen geometry, make the new filter essentially a downscaled and simplified version of the D736 Ph.I.S.I.O.. The modifications to some of the external features result in enhanced ergonomics.

**INDICATION FOR USE:**

The D130 Ph.I.S.I.O. Dideco Kids with 40 micron screen phosphorilcholine coated is recommended for use in the arterial line of the extracorporeal circuit during any procedure that requires cardiopulmonary bypass. The filter is used to trap and remove gaseous emboli as well as particulate debris that maybe introduced through the arterial line. The device should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

**TECHNOLOGICAL CHARACTERISTICS:**

The D130 Ph.I.S.I.O. has the same operating principles and control mechanisms when compared to the D736 Ph.I.S.I.O. unmodified devices. The D130 Ph.I.S.I.O. utilize the same materials, the same filtering media, the same main blood flow path and the same filtering pore size (40 micron) as the unmodified device. The design features of the D130 Ph.I.S.I.O. have been renewed with respect to those of the current D736 Ph.I.S.I.O. Newborn-Infant unmodified device. Furthermore, no change of the intended use has been made for the downscaled and simplified version of the device as result of the design changes with consequent decrease in priming volume and maximum blood flow rate to 0.7. Both devices share the identical manufacturing process. The arterial filter is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

**BIOCOMPATIBILITY TEST RESULTS:**

A complete battery of tests were carried out in accordance with the requirements of ISO 10993-1:2002 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing on the raw materials. Testing was performed on the D130 Ph.I.S.I.O. (accelerated aging). The devices were aged up to three years and tested for Hemolysis, Hemocompatibility, Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity, Sterility, Pyrogenicity and ETO residuals. Package integrity testing was also conducted. The results of the testing met established specifications.

***IN VITRO* TEST RESULTS:**

*In vitro* testing was carried out in accordance with the relevant requirements of "Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submission" Final Guidance for Industry, dated November 29, 2000 for providing the data necessary to demonstrate both substantial equivalence with the unmodified device and show that the device is compliant with safety and effectiveness requirements. The device was aged up to 3 years and tested for operating blood volume, structural integrity test, pressure integrity test, pressure drop, filter flow rate capacity, *in vitro* hemolysis/cell depletion, filtration efficiency, leaching of the coating and air handling characteristics. For comparative purposes all tests, when applicable, were performed on sterilized aged devices comparing the D130 Ph.I.S.I.O. vs. the D736 Ph.I.S.I.O. operated at their related max blood flow. The results of these tests met established specifications. Since the D 736 Ph.I.S.I.O should be considered as a worst case with respect to the overall surface area in blood contact, blood compatibility characterization data presented in D 736 Ph.I.S.I.O. 510(k) (K002493) can be referenced.

**CONCLUSIONS:**

The results of *in vitro* studies demonstrate that the design modifications result in reduced priming volume and pressure drop with an effective filter flow rate capacity at all blood flow rates as compared to the D736 Ph.I.S.I.O. unmodified device. Both filters demonstrated a comparable structural integrity, hemolysis/cell depletion and removal capability of microbubbles as well as air bolus introduced in the circuit. Likewise both filters demonstrated a comparable filtration efficiency with an overall mean percent removal greater than 80% for particles equal to the nominal pore size of the filter (40μ). The D130 Ph.I.S.I.O. filter demonstrated integrity when pressurized over the maximum recommended pressure and no analytical evidence of the possibility of leaching of phosphoriylcholine coating from the D130 Ph.I.S.I.O. was evidenced during the leaching test. The results are in line with expectations because the D130 Ph.I.S.I.O. is smaller in overall size, has a more compact design, and contains a different filter screen design as compared to the unmodified device. The smaller size offers theoretical advantages in terms of reduced priming volume and consequently less hemodilution. A lower priming volume is desirable as it results in advantageous patient hemodynamic, reduced exposure of the blood cells and plasma proteins to large surface areas.

Biocompatibility tests demonstrate that its performance is equivalent to the D736 Ph.I.S.I.O. unmodified device, according to its intended use. Additional testing has demonstrated the effectiveness of production techniques assuring that the newborn arterial filter is sterile and non-pyrogenic

In conclusion test result of this study suggests the D130 Ph.I.S.I.O. arterial filter is equivalent to the D736 Ph.I.S.I.O. arterial filter with respect to device function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2007

Sorin Group Italia S.R.L.
c/o Mr. Barry Sall
Principal Consultant
200 West Street
Waltham, MA 02451-1163

Re: K063255
D130 PH.I.S.I.O. Dideco Kids Neonatal Arterial Filter
Regulation Number: 21 CFR 870.4260
Regulation Name: Cardiopulmonary Bypass Arterial Blood Line Filter
Regulatory Class: II
Product Code: DTM
Dated: December 20, 2006
Received: December 21, 2006

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

FOR Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K063255

Device Name: D130 Ph.I.S.I.O. Dideco Kids Neonatal Arterial Filter with 40 micron screen phosphorylcholine coated

Indications For Use:

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Prescription Use__√___ and/or Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063255